AMENDED IN ASSEMBLY APRIL 23, 2014 AMENDED IN ASSEMBLY MARCH 18, 2014

CALIFORNIA LEGISLATURE—2013-14 REGULAR SESSION

ASSEMBLY BILL

No. 2605

Introduced by Assembly Member Bonilla

February 21, 2014

An act to amend Section 4200.3 of the Business and Professions Code, relating to pharmacy. An act to amend Sections 4022.5, 4040.5, 4043, 4045, 4053, 4060, 4081, 4101, 4105, 4120, 4126, 4149, 4160, 4161, 4162, 4162.5, 4164, 4165, 4166, 4167, 4168, 4169, 4201, 4305.5, 4312, 4331, and 4400 of, and to amend the heading of Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2605, as amended, Bonilla. Pharmacy: sterile drug products. *Pharmacy: third-party logistics providers*.

(1) Under the Pharmacy Law, a violation of which is a crime, the California State Board of Pharmacy licenses and regulates the practice of pharmacy. Existing law restricts the purchase, trade, sale, or transfer of dangerous drugs or dangerous devices, as defined, to licensed wholesalers and other authorized persons. Under the Pharmacy Law, the board licenses and regulates entities, including third-party logistics providers, as wholesalers. The Pharmacy Law defines a "third-party logistics provider" or a "reverse third-party logistics provider" as an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or

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other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs.

This bill would delete from the definition of "third-party logistics provider" or "reverse third-party logistics provider" the requirement that the entity be a licensed wholesaler, and would require a third-party logistics provider of a dangerous drug or dangerous device to be separately licensed by the board as a third-party logistics provider.

(2) The Pharmacy Law requires a person located outside this state that ships, sells, mails, or delivers dangerous drugs or dangerous devices into this state, or sells, brokers, or distributes dangerous drugs or devices within this state to be a licensed nonresident wholesaler.

This bill would, in addition, require a person located outside this state that performs those actions or that warehouses or distributes dangerous drugs or dangerous devices into this state, or warehouses dangerous drugs or devices within this state to be licensed as either a nonresident wholesaler or a nonresident third-party logistics provider. The bill would make conforming changes, and would delete obsolete cross-references and provisions.

- (3) Existing law sets the fees for the issuance and renewal of licenses for wholesalers and designated representatives at specified amounts and authorizes those fees to be increased to specified higher amounts.
 - This bill would instead set the fees at the higher amounts.
- (4) Because a violation of the requirements described in paragraphs (1) and (2) above would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires an applicant for licensure to have, among other things, passed specified national and state examinations. Existing law requires the examination process to be regularly reviewed, as specified, and to meet certain national testing standards. Existing law requires the board to report to the Joint Committee on Boards, Commissions, and Consumer Protection and the Department of Consumer Affairs, as part of its next scheduled review,

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the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination, as specified.

This bill would instead require the board to report the pass rate information described above to the appropriate policy committees of the Legislature and the department.

Vote: majority. Appropriation: no. Fiscal committee: no yes. State-mandated local program: no yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4022.5 of the Business and Professions 2 Code is amended to read:

- 4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.
- (b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's compliance of the wholesaler, third-party logistics provider, or veterinary food-animal drug-retailer's compliance retailer with all state and federal laws and regulations pertaining to practice in the applicable license category.
- 16 SEC. 2. Section 4040.5 of the Business and Professions Code 17 is amended to read:
 - 4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, *third-party logistics providers*, manufacturers, and other entities by receiving, inventorying, *warehousing*, and managing the disposition of outdated or-nonsalable nonsaleable dangerous drugs.
 - SEC. 3. Section 4043 of the Business and Professions Code is amended to read:
 - 4043. (a)—"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by

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law, a wholesaler may not store, warehouse, or authorize the
storage or warehousing of drugs with any person or at any location
not licensed by the board.

- (b) This section shall become operative January 1, 2006.
- SEC. 4. Section 4045 of the Business and Professions Code is amended to read:
- 4045. "Third-party logistics provider" or "reverse third-party logistic provider" means—an entity licensed as a wholesaler an entity that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.
- SEC. 5. Section 4053 of the Business and Professions Code is amended to read:
- 4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a—wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the—wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer.
- (b) An individual *who is at least 18 years of age* may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
- (1) He or she shall be a high school graduate or possess a general education development certificate equivalent.
- (2) He or she shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, *third-party logistics provider*, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all

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of the prerequisites to take the examination required for licensure as a pharmacist by the board.

- (3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
- (A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
- (B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
 - (C) Knowledge and understanding of quality control systems.
- (D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
- (E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.
- (4) The board may, by regulation, require training programs to include additional material.
- (5) The board—may *shall* not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
- (c) The wholesaler, third-party logistics provider, or veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
- (d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
- (e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).
- SEC. 6. Section 4060 of the Business and Professions Code is amended to read:
- 4060. A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does

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1 not apply to the possession of any controlled substance by a
2 manufacturer, wholesaler, *third-party logistics provider*, pharmacy,
3 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian,
4 naturopathic doctor, certified nurse-midwife, nurse practitioner,
5 or physician assistant, if in stock in containers correctly labeled
6 with the name and address of the supplier or producer.

This section does not authorize a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

SEC. 7. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

- (b) The owner, officer, and partner of a pharmacy, wholesaler, *third-party logistics provider*, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.
- (c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.
- 37 SEC. 8. Section 4101 of the Business and Professions Code is 38 amended to read:
- 39 4101. (a) A pharmacist may take charge of and act as the 40 pharmacist-in-charge of a pharmacy upon application by the

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pharmacy and approval by the board. Any pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.

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- (b) A designated representative or a pharmacist may take charge of, and act as, the designated representative-in-charge of a wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer upon application by the wholesaler third-party logistics provider, or veterinary wholesaler, food-animal drug retailer and approval by the board. Any designated representative-in-charge who ceases to act as the designated representative-in-charge at that entity shall notify the board in writing within 30 days of the date of that change in status.
- SEC. 9. Section 4105 of the Business and Professions Code is *amended to read:*
- 4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
- (b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed
- (c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.
- (d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug-retailer or retailer, wholesaler, third-party logistics provider, or the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.
- (e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

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(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

- (f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.
- SEC. 10. Section 4120 of the Business and Professions Code is amended to read:
- 4120. (a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler *or third-party logistics provider* who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler *or third-party logistics provider* pursuant to this chapter without registering as a nonresident pharmacy.
- (b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.
- (c) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.
- (d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.
- SEC. 11. Section 4126 of the Business and Professions Code is amended to read:
- 4126. (a) Notwithstanding any other provision of law, a covered entity may contract with a pharmacy to provide pharmacy

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services to patients of the covered entity, as defined in Section 256b of Title 42 of the United States Code, including dispensing preferentially priced drugs obtained pursuant to Section 256b of Title 42 of the United States Code. Contracts between those covered entities and pharmacies shall comply with guidelines published by the Health Resources and Services Administration and shall be available for inspection by board staff during normal business hours.

- (b) Drugs purchased pursuant to Section 256b of Title 42 of the United States Code and received by a pharmacy shall be segregated from the pharmacy's other drug stock by either physical or electronic means. All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records.
- (c) Drugs obtained by a pharmacy to be dispensed to patients of a covered entity pursuant to Section 256b of Title 42 of the United States Code that cannot be distributed because of a change in circumstances for the covered entity or the pharmacy shall be returned to the distributor from which they were obtained. For the purposes of this section, a change in circumstances includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity.
- (d) A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler *license*, or both a pharmacy and a third-party logistics provider license.
- (e) Neither a covered entity nor a pharmacy shall be required to obtain a license as a wholesaler *or a third-party logistics provider* based on acts reasonably necessary to fully participate in the drug purchase program established by Section 256b of Title 42 of the United States Code.
- SEC. 12. Section 4149 of the Business and Professions Code is amended to read:
- 4149. (a) A nonresident distributor shall not sell or distribute hypodermic needles or syringes in this state without obtaining a license from the board pursuant to Section 4141.
- (b) Notwithstanding subdivision (a), no a license shall be is not required if the nonresident distributor sells or distributes solely

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through a person who is licensed as a wholesaler *or third-party logistics provider* pursuant to Section 4160.
 (c) The Legislature, by enacting this section, does not intend a

- (c) The Legislature, by enacting this section, does not intend a license issued to any nonresident distributor pursuant to this article to serve as evidence that the entity is doing business within this state.
- SEC. 13. The heading of Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code is amended to read:

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Article 11. Wholesalers Wholesalers, Third-Party Logistics Providers, and Manufacturers

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- SEC. 14. Section 4160 of the Business and Professions Code is amended to read:
- 4160. (a) A person—may shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
- (b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
- (c) A separate license shall be required for each place of business owned or operated by a—wholesaler. wholesaler or third-party logistics provider. Each license shall be renewed annually and shall not be transferable.
- (d) Every wholesaler or third-party logistics provider shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance of the wholesaler or third-party logistics provider with state and federal laws governing wholesalers and third-party logistics providers. As part of its initial application for a license, and for each renewal, each wholesaler or third-party logistics provider shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or proposed serve pharmacist the to as designated proposed representative-in-charge. The designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler or third-party logistics provider license without identification of an approved

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designated representative-in-charge for the wholesaler. wholesaler or third-party logistics provider.

- (e) Every-A wholesaler or third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler or third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.
- (f) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.
- (g) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
- SEC. 15. Section 4161 of the Business and Professions Code is amended to read:
- 4161. (a) A person located outside this state that (1) ships, sells, mails, *warehouses*, *distributes*, or delivers dangerous drugs

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or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler. wholesaler or a nonresident third-party logistics provider.

- (b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.
- (c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler *or nonresident third-party logistics provider* from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, *warehoused, distributed*, or delivered to a site located in this state or sold, brokered, *warehoused*, or distributed within this state. A license shall be renewed annually and shall not be transferable.
- (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:
 - (1) Its agent for service of process in this state.
- (2) Its principal corporate officers, as specified by the board, if any.
- (3) Its general partners, as specified by the board, if any.
 - (4) Its owners if the applicant is not a corporation or partnership.
- (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
- (f) A nonresident wholesaler *or nonresident third-party logistics provider* shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
- (g) A nonresident wholesaler *or nonresident third-party logistics provider* shall maintain records of dangerous drugs and dangerous devices sold, traded, *transferred*, *warehoused*, ortransferred

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distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

- (h) A nonresident wholesaler *or nonresident third-party logistics provider* shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler *or nonresident third-party logistics provider* in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler *or nonresident third-party logistics provider* license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
- (i) The board—may shall not issue or renew a nonresident wholesaler or nonresident third-party logistics provider license until the nonresident wholesaler or nonresident third-party logistics provider identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (j) The designated representative-in-charge shall be responsible for the *compliance of the* nonresident—wholesaler's compliance wholesaler or nonresident third-party logistics provider with state and federal laws governing—wholesalers. wholesalers and third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars (\$550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of

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any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

- (*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.
- SEC. 16. Section 4162 of the Business and Professions Code is amended to read:
- 4162. (a) (1) An-applicant, that is not a government owned and operated wholesaler, applicant for the issuance or renewal of a wholesaler-license or third-party logistics provider license, which is not government owned and operated, shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
- (2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the wholesaler *or third-party logistics provider* is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).
- (3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, wholesaler or third-party logistics provider, shall not be required to post a surety bond as provided in paragraph (1).
- (4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
- (b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.
- (c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision

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(a) for all licensed sites under common control as defined in Section 4126.5.

- SEC. 17. Section 4162.5 of the Business and Professions Code is amended to read:
- 4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler *or third-party logistics provider* license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.
- (2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler *or third-party logistics provider* is ten million dollars (\$10,000,000) or-less *less*, in which *case* the surety bond shall be twenty-five thousand dollars (\$25,000).
- (3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler *or third-party logistics provider* who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
- (4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident—wholesaler, wholesaler or third-party logistics provider, shall not be required to post a surety bond as provided in this section.
- (b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.
- (c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

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SEC. 18. Section 4164 of the Business and Professions Code 2 is amended to read:

- 4164. (a) A wholesaler or third-party logistics provider licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all-sales distributions of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.
- (b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.
- (c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.
- (d) As used in this section, "preferential or contract prices" means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.
 - (e) This section shall become operative on January 1, 2006.
- SEC. 19. Section 4165 of the Business and Professions Code is amended to read:
- 4165. A wholesaler or third-party logistics provider licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer

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of the law with all records or other documentation of that sale or transfer.

- SEC. 20. Section 4166 of the Business and Professions Code is amended to read:
- 4166. (a) Any wholesaler that uses the services of any *third-party logistics provider or* carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that *provider or* carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
- (b) Nothing in this section is intended to affect the liability of a—wholesaler wholesaler, third-party logistics provider, or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.
- SEC. 21. Section 4167 of the Business and Professions Code is amended to read:
- 4167. A wholesaler *or third-party logistics provider* shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, on the premises licensed by the board.
- SEC. 22. Section 4168 of the Business and Professions Code is amended to read:
- 4168. A county or municipality-may shall not issue a business license for any establishment that requires a wholesaler or third-party logistics provider license unless the establishment possesses a current wholesaler or third-party logistics provider license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.
- SEC. 23. Section 4169 of the Business and Professions Code is amended to read:
- 4169. (a) A person or entity—may shall not do any of the following:
- (1) Purchase, trade, sell, *warehouse, distribute,* or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a <u>wholesaler</u> wholesaler, third-party logistics provider, or pharmacy.
- (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated,

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as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.
- (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.
- (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.
- (b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.
- (c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
- (d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.
- SEC. 24. Section 4201 of the Business and Professions Code is amended to read:
- 4201. (a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.
- (b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:
- (1) If the applicant is a partnership or other unincorporated association, each partner or member.
- (2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.
- 38 (3) If the applicant is a limited liability company, each officer, manager, or member.

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(c) In any case where If the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and—where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

- (d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.
- (e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, *third-party logistics provider*, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, *third-party logistics provider*, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.
- (f) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.
- (g) Notwithstanding any other provision of law, the wholesale wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
- (h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

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(i) Notwithstanding any other-provision of law, the veterinary food-animal drug retailer license shall authorize the holder-thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

- (j) For licenses referred to in subdivisions (f), (g), (h), and (h), (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.
- (j) This section shall become operative on July 1, 2001.
- SEC. 25. Section 4305.5 of the Business and Professions Code is amended to read:
- 4305.5. (a) A person—who has obtained that is licensed as a license to conduct a wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.
- (b) A person-who has obtained that is licensed as a license to conduct a wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, who that willfully fails to notify the board of the termination of employment of the designated representative-in-charge, representative-in-charge at its licensed place of business, and who that continues to operate the licensee place of business in the absence of the designated representative-in-charge for that location, place of business shall be subject to summary suspension or revocation of his or her its license to conduct as a wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug-retailer. retailer at that place of business.
- (c) A designated representative-in-charge of a wholesaler wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, licensed place of business, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.
 - (d) This section shall become operative on January 1, 2006.

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SEC. 26. Section 4312 of the Business and Professions Code is amended to read:

4312. (a) The board may cancel the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

- (b) In-If the-event that the license of a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer is cancelled canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.
- (c) If a wholesaler, *third-party logistics provider*, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, *third-party logistics provider*, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, *third-party logistics provider*, pharmacy, or veterinary food-animal

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drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, third-party logistics provider, pharmacy, or veterinary food-animal drug retailer.

- (d) In If the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.
- (1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.
- (2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.
- (3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.
- (e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.
- 36 (f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.
- 38 SEC. 27. Section 4331 of the Business and Professions Code 39 is amended to read:

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4331. (a) A person who is neither a pharmacist nor a designated representative and who-takes charge does either of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices the following, except as otherwise provided in this—chapter chapter, is guilty of a misdemeanor: misdemeanor:

- (1) Takes charge of a wholesaler, third-party logistics provider, or veterinary food-animal drug retailer.
- (2) Coordinates the warehousing or distribution of dangerous drugs or dangerous devices or dispenses a prescription or furnishes dangerous devices.
- (b) A person-who has obtained licensed as a license to conduct a veterinary food-animal drug retailer and who that fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.
- (c) A person-who has obtained licensed as a license to conduct a wholesaler-and who or third-party logistics provider that fails to place in charge of that wholesaler or third-party logistics provider a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.
 - (d) This section shall become operative on January 1, 2006.
- SEC. 28. Section 4400 of the Business and Professions Code, as added by Section 9 of Chapter 565 of the Statutes of 2013, is amended to read:
- 4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:
- (a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

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(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

- (c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).
- (d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).
- (f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).
- (g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).
- (h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).
- (2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).
- (i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be-two

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hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

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- (2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150).
- (j) (1) The application fee for a nonresident—wholesaler's wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).
- (2) For nonresident wholesalers—who or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be—six—hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to no less than five hundred fifty dollars (\$550).
- (3) The annual renewal fee for a nonresident—wholesaler's wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780) and may be decreased to no less than six hundred dollars (\$600).
- (k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.
- (1) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

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(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

- (n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.
- (r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (u) The fee for issuance or renewal of a nongovernmental sterile compounding pharmacy license shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

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(v) The fee for the issuance or renewal of a nonresident sterile compounding pharmacy license shall be seven hundred eighty dollars (\$780). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) This section shall become operative on July 1, 2014.

SEC. 29. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.

SECTION 1. Section 4200.3 of the Business and Professions Code is amended to read:

4200.3. (a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and

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shall use only the written and practical examination developed by
 the board.

- (c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.
- (d) The board shall work with the Office of Professional Examination Services or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.
- (e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.
- (f) The board shall report to the appropriate policy committees of the Legislature and the department, as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.